UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

JUSTIN WAYNE HEATH,)	
Plaintiff,)	
)	
V.)	Case No. 3:19-cv-0803
)	Judge Aleta A. Trauger
C.R. BARD INCORPORATED and)	
BARD PERIPHERAL VASCULAR)	
INCORPORATED,)	
)	
Defendants.)	

MEMORANDUM & ORDER

The defendants (collectively, "Bard") have filed Motion in Limine to Exclude Evidence or Testimony Relating to the Prophylactic/Off-Label Use of Bard Filters in Bariatric Patients and Other Purported "Bad Acts" (Doc. No. 133), to which plaintiff Justin Wayne Heath has filed a Response (Doc. No. 154). For the reasons set out herein, the motion will be granted in part and denied in part.

Heath is a Tennessee patient who was implanted with a Bard device, the G2 inferior vena cava ("IVC") filter, to prevent blood clots from reaching his lungs. The decision to implant the device was made after Heath developed deep vein thrombosis ("DVT") in the wake of gastric lap band surgery to treat his morbid obesity. Several years later, the filter came unfixed from its original installation point and migrated into his heart, causing damage and requiring surgical intervention. Heath has sued Bard, alleging that the filter was poorly designed and that Bard failed to communicate the risks associated with the filter adequately to the medical community.

Bard asks the court to "exclude any reference, evidence, or argument concerning the prophylactic or off-label use of Bard filters in bariatric patients." Off-label use of a medical device is the use of the device for a purpose other than the purpose for which it was "specifically [authorized] by the Food and Drug Administration." *United States ex rel. Modglin v. DJO Glob. Inc.*, 48 F. Supp. 3d 1362, 1369 (C.D. Cal. 2014). Off-label use of drugs and devices is common and, as long as the use is directed by an appropriate healthcare provider, is a well-established, ordinary component of healthcare in the United States. Manufacturers, however, are not permitted to market their products for off-label uses. *Id.* According to Bard, "[a]fter Bard's Recovery filter (the first-generation retrievable filter) entered the market, bariatric physicians began using retrievable filters prophylactically before bariatric surgeries," which was an off-label use. (Doc. No. 134 at 1.) The parties agree, however, that that is not what happened here, because Heath developed his DVT *before* the filter was implanted, and the use of the filter in such a situation was consistent with the filter's FDA clearance.

In its motion, Bard suggests that Heath intends to present evidence of off-label use of Bard filters at trial, in an attempt to paint Bard in a bad light. In particular, Bard identifies four emails that, it argues, would be used for that purpose. (Doc. Nos. 135-3, 135-5, 135-6, 136-7.) Heath responds that he has "no intention" of attempting to show that there was a problem with off-label use of the G2 filter. (Doc. No. 154 at 3.) Rather, he says, he wishes to introduce the relevant emails to demonstrate Bard's knowledge of the risks associated with the use of the G2 filter, including heightened risks in bariatric patients, and he notes that two of the emails were admitted in other trials this year. With regard to three of the four emails, Heath's response is persuasive. Each of

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¹ Bard also asks the court to exclude reference, evidence, or argument concerning unidentified "other purported 'bad acts.'" The court takes this portion of the request to refer to the fact that some of the evidence identified by Bard for potential exclusion includes language that reflects poorly on Bard personnel for reasons other than any promotion of off-label use.

those emails contains—or at least arguably contains, considering the vagueness of the language used—information relevant to Bard's consideration of the risks associated with the use of IVC filters. (See Doc. Nos. 135-3, 135-6, 136-7.) One email exchange, however—the June 9, 2004 exchange between Robert Carr and Jason Greer—does appear to lack any relevant content. Rather, it consists solely of (1) a short billing-related discussion of prophylactic use of IVC filters and (2) a callous (and uncreative) joke by Carr at the expense of obese people. (See Doc. No. 135-5.) Any

limited probative value of that email is outweighed by its potential for prejudice.²

If Heath did choose to focus on off-label use at trial, that would certainly be inappropriate, given that it has nothing to do with this case. There is, however, no reason to think that he intends to do so, and he has identified appropriate, relevant purposes for introducing the pieces of evidence at issue, except one. Bard's Motion in Limine to Exclude Evidence or Testimony Relating to the Prophylactic/Off-Label Use of Bard Filters in Bariatric Patients and Other Purported "Bad Acts" (Doc. No. 133) is therefore **GRANTED** in part and **DENIED** in part. The June 9, 2004 email exchange found at Doc. No. 135-5 is **EXCLUDED** from trial.

It is so **ORDERED**.

ALETA A. TRAUGER // United States District Judge

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² In contrast, the email exchange on May 27, 2004, which contains another, similar joke by Carr, contains plainly relevant discussion of filter risks in obese patients that outweighs any prejudice associated with *that* joke.